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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,583	03/18/2004	Edgardo Costa Maiani	DID1046US	7264
9561 7590 07/08/2010 POPOVICH, WILES & O'CONNELL, PA 8519 EAGLE POINT BLVD Suite 180 LAKE ELMO, MN 55042			EXAMINER CHAPMAN, GINGER T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,583

Applicant(s)

MAIANTI ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2010.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 7 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 06 January 2009 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

1. Claims 1-3 and 7 are pending in the application.

Response to Arguments

2. Applicant's arguments filed 7 April 2010 have been fully considered but they are not persuasive. Applicant argues the following:
 3. Applicant interprets the Office action as construing Raible's housing and pump motor as a monolithic housing 12 comprising an "integrated pump/heat exchanger/membrane oxygenator" component ("P/HE/MO"; column 5, lines 22-24) to include portion 14 "motor drive" component ("M/D"; column 5, lines 24-25) as part of the housing; Raible discloses that the pump/heat exchanger/membrane oxygenator component is disposable and the motor drive component is reusable such that the P/HE/MO is a separate component from the M/D component; therefore Applicant believes that the examiner has concluded that the motor drive portion 14 to be part of the monolithic housing 12.
 4. These arguments are not persuasive for the following reasons:
 5. Applicant's arguments are narrower than the claim language, thus Applicant's arguments are not commensurate in scope with the claims as presently written.
 6. The examiner agrees that the pump/heat exchanger/membrane oxygenator is a separate component from the motor drive component; however, the examiner does not conclude that the portion 14 is part of the monolithic housing; the examiner's position is that portion 14 is positioned within the monolithic housing. In other words, the portion 24 of the housing 12 which is positioned at the bottom of the housing 12 defines the portion within which 14 is

positioned because the cavity 24 at the bottom of the housing defines where the pump motor drive is contained within the housing.

7. Claim 1 as presently written recites, "a monolithic housing including a first portion positioned at a top of the monolithic housing for defining the bubble trap, a second portion positioned at a bottom of the monolithic housing for defining the blood pump";

8. The dictionary definition of "defining":

Function: *verb*

Inflected Form(s): **de-fined; de-fin-ing**

Etymology: Middle English, from Latin *definire*, from *de-* + *finire* to limit, end, from *finis* boundary, end

Date: 14th century

transitive verb **1 a** : to determine or identify the essential qualities or meaning of <whatever defines us as human> **b** : to discover and set forth the meaning of (as a word)
c : to create on a computer <define a window> <define a procedure>
2 a : to fix or mark the limits of : DEMARCATÉ <rigidly *defined* property lines> **b** : to make distinct, clear, or detailed especially in outline <the issues aren't too well *defined*>
3 : CHARACTERIZE, DISTINGUISH <you define yourself by the choices you make — *Denison University Bulletin*>*intransitive verb* : to make a definition

9. shaping: any process serving to define the shape of something

10. defined - showing clearly the outline or profile or boundary; "hills defined against the evening sky"; "the setting sun showed the outlined figure of a man standing on the hill"

11. —**Synonyms**

3. state, name, describe, detail, enumerate.

12. The claim as written does not require the pump to be part of the housing; the claim only requires the housing to include a portion at the bottom for defining the pump. It appears that Applicant is arguing that, because the pump 14 is removable from the bottom portion 24 of the housing 12, it is not part of the housing, however the claim as presently written does not require

the pump to be part of the housing, the claim only requires a portion positioned at the bottom of the housing *for defining* the blood pump.

13. Raible discloses that the portion 24 of the monolithic housing positioned at the bottom of the housing defines a cavity which encloses the motor drive portion of the pump which drives the pump impellers. Raible discloses at column 5, lines 46-52:

14. With particular reference to FIGS. 3-6, the P/HE/MO component 12 may comprise a rigid housing 18 which includes an outer wall 20 and an inner wall 22. The housing 18 defines an elongate hollow inner cavity 24 which extends upwardly from an opening 26 formed in the bottom of the P/HE/MO component 12. The elongate, hollow inner cavity 24 of the P/HE/MO component 12 is sized and configured to receive therewithin, and rest upon, the upstanding support member 16 of the M/D component 14.

15. Thus Raible meets the claim as presently written.

16. As per MPEP §§ 2173.05(a) [R-3], During patent examination, the pending claims must be given the broadest reasonable interpretation consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969).

17. The instant Specification at paragraphs [0009, 0010, 0015] discloses that,

18. The integrated device includes a monolithic housing having a first portion for defining the bubble trap, a second portion for defining the blood pump, a third portion for defining the heat exchanger, a fourth portion for defining the oxygenator and a fifth portion for defining the arterial blood filter. The blood pump may comprise a centrifugal pump that is positioned within the monolithic housing such that an axis of the centrifugal pump is horizontal.

19. Centrifugal pump 4 has a transparent enclosure which defines an outlet connector 4b which is connected to delivery duct 4a, connected to provide blood from centrifugal pump 4 to an inlet connector 5a of heat exchanger 5.

20. Raible discloses a pump positioned within the monolithic housing connected to an inlet of a heat exchanger; Raible discloses a portion positioned at a bottom of the monolithic housing for defining the blood pump, therefore, although the pump portion 14 of Raible is removable from the housing, the housing still comprises a portion 24 positioned at a bottom of the housing for defining a blood pump 14 that is positioned within the housing 12. Therefore the examiner respectfully traverses Applicants' arguments and maintains the prior art rejections of the rejected claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Raible (US 5,770,149).

3. With respect to claim 1, as best depicted in Figures 1-3, Raible discloses an integrated device 10 (Figure 1) (col. 1, lines 45-49 and lines 59-60) Figures 1-3, for oxygenating and filtering blood flowing through an extracorporeal circuit comprising:

4. a bubble trap 30, at column 6, lines 19-27 teaching that the cavity 30 comprises bubble outlet port 31 and associated cap 33 member at the top of the cavity 30 to permit the air bubbles collecting at the top of cavity 30 to be vented or aspirated and removed through the air bubble port outlet 31 of chamber 30, therefore the examiner is considering the cavity 30 to be a bubble trap since it performs the function of trapping, i.e. collecting and venting the trapped bubbles; (the examiner notes that Raible also discloses the bottom portion of the cavity 30 below the bubble outlet port 31 may also house the impeller 40 of the pump 14), an inlet 28 for receiving venous blood and an outlet 52 for supplying venous blood, teaching at col. 6, lines 34-38 that the bottom portion of the cavity 30 is in fluid communication with an annular blood outflow space 52, i.e. an "outlet" through which venous blood may exit the cavity 30, therefore the examiner is considering the blood outflow port 52 at the bottom of cavity 30 to be "an outlet for supplying venous blood" because the outflow port supplies venous blood which flows from cavity 30 down into the next portion downstream of the cavity 30 of the device;
5. a blood pump 14, at column 6, lines 44-63 and Figures 2 and 3 teaching pump 14 motor drive and the pump comprises elements 48, 46, 44, 42, 40, 38; the impeller 48 and impeller assembly 38 are housed with the bottom portion of cavity 30, therefore the inlet 28 which supplies blood to cavity 30 also provides an inlet 28 to the portion 38, 40 of the pump because the pump receives venous blood via inlet 28, and an outlet 52 because the blood outflow port 52 of cavity 30 supplies venous blood flowing past the pump 14 impellers 40 down into the next portion downstream of the impellers 40, and the blood outflow port i.e. outlet 52 is positioned at a top of the blood pump 14 because the pump 14 is positioned below the outlet 52 and thus the outlet is positioned at a top of the blood pump;

6. a heat exchanger 54 (col. 7, line 7) having a blood inlet 50 (col. 7, lines 57-58: teaching that blood flows out of outlet 52 into heat exchanger 54 cavity 50, therefore the examiner is considering the inlet port of heat exchanger cavity 50 where the blood flows from outlet 52 into cavity 50 to be the inlet, said inlet 50 connected 52 to receive venous blood from outlet 52 of the pump 38, see column 7, lines 53-60, teaching blood flowing from inlet 28 into bubble trap 30 past impellers 38 of the pump 14 through outflow 52 into heat exchange cavity 50 including heat exchangers 54) and a blood outlet 70 (col. 8, lines 1-5 and col. 7, lines 61-67);

7. The examiner notes that Raible discloses the circuit in terms of blood flowing into and out of the cavities without expressly disclosing that each cavity necessarily and inevitably must comprise inlets and outlet through which blood must flow into and out of the cavities; therefore the examiner is considering the inlet to each cavity and the outlet from each cavity of Raible as comprising inlets and outlets, although not explicitly labeled with reference characters in the disclosure of Raible. An oxygenator 74 (col. 8, line 13) having an inlet 72 (col. 8, lines 1-13) connected to receive venous blood from the outlet 50 of the heat exchanger 54 and an outlet 72 for supplying oxygenated blood; an arterial blood filter having an inlet connected to receive oxygenated blood from the outlet of the oxygenator and an outlet for supplying filtered oxygenated blood (Figures 9a, 9b; column 12, lines 55-57; lines 66 to column 13, lines 1-5); and a monolithic housing 12 Figs. 1 and 2 (col. 5, line 22) including first portion 30 (figure 3) positioned at the top of the monolithic housing (fig. 1) for defining a bubble trap 30, 31, a second portion 24 (fig. 3) positioned at the bottom 13 of the monolithic housing 12 for defining the blood pump 14 (see Figure 2: 16, 17, 48 and Figure 3: elements 48, 46, 44, 42, 40, 38), a third portion 50 for defining the heat exchanger 54, a fourth portion 70, 72 for defining the arterial

blood filter, wherein the integrated device does not comprise a venous reservoir (column 12, lines 7-23, Figure 8: teaching a separate embodiment and where an optional venous reservoir may or may not be included depending on the intended use of the device determined by a treating physician on a case by case basis, for example, for surgical drainage one may select to include an optional reservoir or can select to omit it).

8. With respect to claim 2, Raible discloses the blood pump 14 comprises a centrifugal pump (c. 6, line 45).
9. With respect to claim 7, Raible teaches monolithic housing 12 is configured such that blood flowing through the extracorporeal circuit is directed through the bubble trap (outlet 33, 31 of chamber 30) before the blood enters the blood pump (col. 6, lines 22-27).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12.

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible in view of Israeliev (US 5,924,848).

14. With respect to claim 3, Raible discloses the claimed invention except for the horizontal axis. Raible discloses the centrifugal pump has an axis and is positioned within the monolithic device such that the axis of the pump is vertical (c. 10, l. 430, thus providing motivation for a centrifugal pump having an axis.

15. Israeliev teaches a centrifugal pump for extracorporeal blood circuit in which the axis of the pump may be either horizontal or vertical (c. 3, ll. 58-59); thus teaching that either horizontal or vertical rotation of axis is suitable for use in an extracorporeal device and thus appears to be an obvious modification within the skill of one of ordinary skill in the art to select an orientation depending on the desired configuration of the components comprising the device.

16. When the axis of rotation of the pump is horizontal, a pump outlet would perform as though the outlet is on the top, when the axis is vertical, the outlet would perform as though it were tangential. Therefore the substantially identical pump can provide either axis of rotation and it would be a matter for the designer to select one of these two axes of rotation depending on how the designer wishes to configure the device and thus is an obvious modification.

17. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide either a horizontal or vertical axis since both perform the substantially identical function in the substantially identical manner and it would thus be a matter of obvious design choice of the designer to select one of these known orientations as taught by Israeliev in the circuit of Raible since Israeliev states, at c. 3, ll. 54-60 that the benefit of using

such a centrifugal pump is that it remains stable when the direction of the pump's axis of rotation is changed when the position of the device's housing is changed to allow for flexibility in positioning the pump.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
06/29/10

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761